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EXAMINER	
ROMEO, DAVID S	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/805,805	JING ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,11 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,11 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed July 17, 2003 has been entered. Claims 1-8, 10, 11, 44 are pending.

Based on an inspection of the 60/188,786 parent provisional application, the examiner has concluded that SEQ ID NO: 1 and ATCC deposit no. PTA-1882 in the present application are not supported by the disclosure in the 60/188,786 parent provisional application because SEQ ID NO: 1 and ATCC deposit no. PTA-1882 are not disclosed in the manner provided by 35 U.S.C. 112, first paragraph, in the 60/188,786 parent provisional application. Accordingly, the subject matter defined in claims 1, 2, 4-8, 10, 11, 44, as it pertains to SEQ ID NO: 1 and ATCC deposit no. PTA-1882 has an effective filing date of 03/13/2001.

Applicant argues that only the nucleotide sequence of SEQ ID NO: 1 is not entitled to the benefit of the filing date of the 60/188,786 parent application. Applicant's arguments, including the discussion in sections 3 and 5, have been fully considered but they are not persuasive. ATCC deposit no. PTA-1882 is not disclosed in the manner provided by 35 U.S.C. 112, first paragraph, in the 60/188,786 parent application, because there is no disclosure of ATCC deposit no. PTA-1882 in the 60/188,786 parent application. It is acknowledged the 60/188,786 parent application discloses the coding sequence (nucleotides 610-1242) of SEQ ID NO: 1.

Claim Rejections - 35 USC § 112, first paragraph

Claims 1-8, 10, 11, 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the genus of molecules defined by claim amended claim 1 is not highly variant, and that one of ordinary skill in the art could readily determine the scope of the claimed invention. Applicant's arguments have been fully considered but they are not persuasive.

Amended claim 1 encompasses an isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes under at least moderately stringent conditions to the complement of an isolated nucleic acid molecule comprising a nucleotide sequence comprising the coding sequence of SEQ ID NO: 1, an isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes under at least moderately stringent conditions to the complement of an isolated nucleic acid molecule comprising a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2, an isolated nucleic acid molecule comprising a nucleotide sequence that is complementary to the nucleotide sequence of an isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes under at least moderately stringent conditions to the complement of an isolated nucleic acid molecule comprising a nucleotide sequence comprising the coding sequence of SEQ ID NO: 1, and an isolated nucleic acid molecule comprising a nucleotide sequence that is complementary to the nucleotide sequence of an isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes under at

least moderately stringent conditions to the complement of an isolated nucleic acid molecule comprising a nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 2. The claims are drawn to a genus of nucleic acid molecules that is defined only by some level of nucleotide similarity encompassed by the term "hybridizes under at least moderately stringent conditions." The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number nucleotide substitutions, deletions, insertions and/or additions that may be made to such hybridizing nucleic acid molecules. No common structural attributes identify the members of the genus. Thus, the genus is highly variant. The specification and claim do not provide any guidance as to what changes should be made. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus and because the genus is highly variant, SEQ ID NO: 1 and polynucleotides encoding SEQ ID NO: 2, alone, are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a

partial structure in the form of some level nucleotide sequence identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide an adequate written description of the claimed genus.

Applicant argues that the genus of molecules encompassed amended claim 2 is not highly variant. Applicant's arguments have been fully considered but they are not persuasive.

The discussion above regarding the specification not providing an adequate written description of the claimed genus encompassed by amended claim 1, also applies to an isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes under at least moderately stringent conditions to the complement of an isolated nucleic acid molecule comprising a region of the nucleotide sequence of SEQ ID NO: 1, or the DNA insert in ATCC deposit number PTA-1882, encoding a polypeptide fragment of SEQ ID NO: 2 of at least 50 amino acid residues in amended claim 2, because the scope of amended claim 2 is broader than the scope of amended claim 1, and if the specification does not provide an adequate written description of the claimed genus in amended claim 1, then the specification does not provide an adequate written description of the claimed genus in amended claim 2.

In addition, amended claim 2 encompasses an isolated nucleic acid molecule comprising a region of the nucleotide sequence of SEQ ID NO: 1, or the DNA insert in ATCC deposit number PTA-1882, encoding a polypeptide fragment of SEQ ID NO: 2 of at least 50 amino acid residues. The structure of the isolated nucleic acid molecule is

unlimited beyond the region encoding any and/or all 50 amino acid fragments of SEQ ID NO: 2. The claims do not require that the amino acid fragment possess any particular biological activity. Thus, the claims are drawn to a genus of nucleic acid molecules that is defined only by any and/or all 50 amino acid fragments of SEQ ID NO: 2. The specification and claim do not place any limit on the number of nucleotide additions that may be made to the portion encoding any and/or all 50 amino acid fragments of SEQ ID NO: 2. The specification and claim do not provide any guidance as to what additions should be made. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. The genus is highly variant because the structure of the isolated nucleic acid molecule is unlimited beyond the region encoding any and/or all 50 amino acid fragments of SEQ ID NO: 2. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of any and/or all 50 amino acid fragments of SEQ ID NO: 2. The structure of the isolated nucleic acid molecule is unlimited beyond the region encoding any and/or all 50 amino acid fragments of SEQ ID NO: 2. The claims do not require that the amino

acid fragment possess any particular biological activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed. The specification does not clearly allow persons of ordinary skill in the art to recognize that Applicants invented what is claimed. The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides and/or polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of making or isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating or making it. The compound itself is required. One cannot describe what one has not conceived. Therefore, only nucleic acid molecules comprising the nucleotide sequence of SEQ ID NO: 1 or nucleic acid molecules encoding the amino acid sequence of SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. These arguments also apply to "(b)" of claim 3, and any and/or all embodiments dependent upon "(b)" of claim 3.

With respect to amended claim 3, Applicant argues that the present specification teaches the SEQ ID NO: 1 and SEQ ID NO: 2 (Figures 1A-1B), that FGF-L shares a high degree of amino acid sequence identity with several other FGFs, that regions that are tolerable to conservative amino acid substitution can be identified by performing

sequence comparisons. Applicant's arguments have been fully considered but they are not persuasive.

The claims are drawn to nucleic acid molecules encoding polypeptides having at least 85% sequence identity with SEQ ID NO: 2. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of nucleic acid molecules that is defined only by polypeptides having at least 85% sequence identity with SEQ ID NO: 2.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Although it might be obvious to the skilled artisan to make sequence comparisons and make amino acid substitutions based on that comparison, the written description does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed. One shows that one is 'in possession' of the

invention by describing the invention, with all its claimed limitations, not that which makes it obvious.

The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

Claims 1-8, 10, 11, 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. .

Applicant argues that the presently amended claims are not overly broad, and that in view of the specification's teachings and knowledge in the art it would not require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. Applicant's arguments have been fully considered but they are not persuasive.

The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. The skilled artisan is left to extensive experimentation wherein such variant polynucleotides and polypeptides are randomly made and through trial and error experimentation is left to determine how such variants can be used. Moreover, there is a

lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. Furthermore, there are no working examples of such variant polynucleotides and polypeptides, and the knowledge of one FGF's structure and function does not provide predictability about function of a structurally related FGF.

The current claim limitations are analogous to those of claim 7 of U.S. Patent No. 4,703,008, which was held to be invalid under 35 U.S.C. § 112, first paragraph, for want of enablement in Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd., 18 USPQ 2d, 1016 (CAFC, 3/5/91, see page 1026, section D). In that instance a claim to a nucleic acid molecule encoding a polypeptide having an amino acid sequence sufficiently duplicative of the amino acid sequence of erythropoietin (EPO) so as to have a specified biological activity was held to be invalid under 35 U.S.C. § 112, first paragraph, for want of enablement. This limitation is analogous to the hybridization and % identity limitations of the instant claims. The disclosure upon which claim 7 of U.S. Patent No. 4,703,008 was based described a recombinant DNA encoding EPO and a few analogs thereof. That disclosure differs from the instant specification because, whereas the instant specification describes a DNA encoding a FGF-L, it does not describe even a single variant thereof. The court held that what is necessary to support claims of this breadth is a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims. For DNA sequences, that means disclosing how to make and use enough sequences to justify the grant of the patent protection sought in the instant claims. As indicated, the instant specification is even more limited than the '008 patent because it

describes only a single protein and no analogs or mutants thereof and, therefore, provides even less support than the '008 specification for claims of comparable scope and which were held to be invalid in that patent.

To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of work that is described in the instant application but a substantial inventive contribution on the part of a practitioner, which would involve determining the functional and structural information necessary to practice the full scope of the claimed invention. It is this additional characterization that constitutes undue experimentation. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not without actually making and testing them then the instant application does not support the breadth of the claims. As mentioned previously, there is a lack of predictability in the art.

Claim Rejections - 35 USC § 112, second paragraph

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4-8, 10, 11, 44 are indefinite over the recitation of "moderately stringent conditions." Applicant argues that the specification defines the meaning of the terms at page 16, lines 3-9, and at page 15, lines 1-8. Applicant's arguments have been fully considered but they are not persuasive. The present specification at page 16, lines

3-9, and at page 15, lines 1-8, does not reasonably apprise one of ordinary skill in the art of the metes and bounds of the term. The examples of the conditions at page 16, lines 3-9, and at page 15, lines 1-8, are merely exemplary and are not intended to limit the meaning of the terms of the claims.

Claim 10 is indefinite because it recites the term "FGF-L". Applicant argues that an explicit definition of "FGF-L polypeptide" is provided at page 9, lines 21-26, of the present specification, and that an explicit definition of the term FGF-L gene is provided in the specification at page 7, lines 22-26. Applicant's arguments have been fully considered but they are not persuasive. The present specification at page 9, lines 21-26, intends the term "FGF-L polypeptide" to encompass "related polypeptides." The present specification at page 7, lines 22-26, intends the term "FGF-L gene" to encompass "nucleic acid molecules as defined herein." Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "FGF-L," "related polypeptides," or "nucleic acid molecules as defined herein" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claim Rejections - 35 USC § 102

Claims 1, 2, 4-6, 8, 11 are rejected under 35 U.S.C. 102(a and/or b) as being anticipated by Koga (cited by Applicants).

This rejection is being made under 102(a) because the 60/188,786 parent application discloses the coding sequence (nucleotides 610-1242) of SEQ ID NO: 1.

This rejection is being made under 102(b) because SEQ ID NO: 1 and ATCC deposit no. PTA-1882 in the present application are not supported by the disclosure in the 60/188,786 parent provisional application. Hence, any and/or all embodiments of the present claims other than the coding sequence (nucleotides 610-1242) of SEQ ID NO: 1 are not supported by the disclosure in the 60/188,786 parent provisional application.

Applicant argues that Koga's nucleic acid molecule could not hybridize under at least moderately stringent conditions to a nucleic acid molecule encompassed by the present claims because in order for a nucleic acid molecule to anticipate the pending claims it must comprise a nucleotide sequence that is about 79% identical to nucleotides 610-1242 of SEQ ID NO: 1, to a nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 2, or to a nucleic acid molecule comprising a region of the nucleotide sequence of SEQ ID NO: 1 or the DNA insert of ATCC deposit no. PTA-1882 encoding a polypeptide fragment of SEQ ID NO: 2 of at least 50 amino acid residues. Applicant's arguments have been fully considered but they are not persuasive. Page 16, lines 8-9, of the present specification is merely exemplary and is not intended to and does not limit the claims in any way. Accordingly, Koga's nucleic acid molecule would hybridize in the absence of evidence to the contrary. Further, the examiner deems the term "about a 21% mismatch" at page 16, lines 8-9, to encompass the mismatch between Koga's nucleic acid molecule and the claimed nucleic acid molecule. Applicant's argument that Koga's nucleic acid molecule shares an overall sequence identity of 52.9% with SEQ ID NO: 1, ignores the Best Local Similarity of 74.2% and the attendant hybridization conferred thereby. As mentioned previously, the term "at least moderately stringent conditions" is vague and indefinite. Consequently, Koga's nucleic acid molecule would hybridize

considering an overall sequence identity of only 52.9% with SEQ ID NO: 1, in the absence of evidence to the contrary. Furthermore, amended claim 2 encompasses a nucleic acid molecule that hybridizes to only a 150 nucleotide fragment of SEQ ID NO: 1 or the DNA insert of PTA-1882, and the % identity of nucleotides 790-939 of SEQ ID NO: 1 is greater that 83% identical, i.e., 125 matches out of 150, to the corresponding region of Koga's nucleic acid molecule, which exceeds the 79% identity limitation improperly read into to the claims by Applicant.

Claims 1-8, 10, 11, 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Jeffers (a8).

Applicant argues that Applicant has not had access to the applications from which Jeffers claims priority. Pursuant to 37 CFR 1.104(d)(2) Applicant makes a request that the examiner make a determination as to whether the full-length nucleotide sequence is disclosed in the applications from which Jeffers claims priority. Applicant argues that in the absence of such a determination Jeffers is not available as prior art. Applicant's arguments have been fully considered but they are not persuasive.

Jeffers is a pending published application. According to 37 CFR 1.14(c)(1)(i), if a U.S. patent application publication or patent incorporates by reference, or includes a specific reference under 35 U.S.C. 119(e) or 120 to, a pending or abandoned application, a copy of that application-as-filed may be provided to any person upon written request including the fee set forth in § 1.19(b)(1). Accordingly, Applicant has access to the applications from which Jeffers claims priority. 37 CFR 1.104(d)(2) pertains to a rejection in an application based on facts within the personal knowledge of an employee

of the Office, and it is not germane to the present rejection because the present rejection is based on a prior art reference and it is not based on facts within the personal knowledge of an employee of the Office. As indicated in the last Office action, the examiner has already made a determination as to whether the full-length nucleotide sequence is disclosed in the applications from which Jeffers claims priority.

Claims 1, 4, 5, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier (cited by Applicants).

Applicant argues that because the Hillier's nucleic acid molecule lacks any portion of the FGF-L open reading frame, Hillier cannot anticipate claim 1. Applicant's arguments have been fully considered but they are not persuasive. The limitation "the DNA insert in ATCC Deposit No. PTA-1882" is not limited to a portion of the FGF-L open reading frame. Furthermore, SEQ ID NO: 1 is a "nucleic acid molecule comprising a nucleotide sequence encoding the polypeptide as set forth in SEQ ID NO: 2" and Hillier's nucleic acid molecule would hybridize to SEQ ID NO: 1, as indicated in the last Office action.

Claim Rejections - 35 USC § 101

Claims 1-8, 10, 11, 44 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant argues that FGF-L is a member of the FGF family of proteins, that FGF family members have substantial, real world use. Applicant's arguments have been fully

considered but they are not persuasive. As indicated in the last Office action, Galzie and Koga are evidence that FGF family members lack a common utility applicable to all members of this family. Furthermore, one skilled in the art recognizes that although structural similarity can serve to classify a protein as related to other known proteins this classification is insufficient to establish a function or biological significance for the protein.

Applicant argues that one of ordinary skill in the art would recognize that FGF-L is the human ortholog of XFGF-20. Applicant's arguments have been fully considered but they are not persuasive. Although Koga suggest that correct expression of XFGF-20 during gastrulation is required for the formation of normal head structures in Xenopus laevis during embryogenesis and that expression of the Xbra gene mediates this phenomenon (Abstract), the present specification provides no specific information on the expression or significance of the FGF-L nucleic acid molecule or polypeptide.

Claims 1-8, 10, 11, 44 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant argues that present application contains an assertion of a specific and substantial asserted utility or a well established utility. Applicant's arguments have been fully considered but they are not persuasive. As Applicants recognize, a rejection under § 112, first paragraph, may be maintained on the same basis as a lack of utility rejection under § 101. A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C.

112, first paragraph. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112. Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it. As such, a rejection properly imposed under 35 U.S.C. 101 should be accompanied with a rejection under 35 U.S.C. 112, first paragraph. The 35 U.S.C. 112, first paragraph, rejection set out a separate rejection that incorporates by reference the factual basis and conclusions set forth in the 35 U.S.C. 101 rejection. A 35 U.S.C. 112, first paragraph, rejection should be imposed or maintained when an appropriate basis exists for imposing a rejection under 35 U.S.C. 101.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 3-8, 10, 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Support for the combination of the substitutions and/or truncations with the combination of at least 85% identical and comprises at least 50 amino acid residues cannot be found in the disclosure as originally filed and the introduction of such a limitation raises the issue of new matter. Support for the combination of at least 85% identical and comprises at least 50 amino acid residues

cannot be found in the disclosure as originally filed and the introduction of such a limitation raises the issue of new matter.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

5

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
OCTOBER 15, 2003